IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, Plaintiff, *ex rel.* Leanne Houston, Relator, v. Medtronic, Inc., Defendant.	)	Civil Action No. 2:20-3367-BHH **ORDER**

This matter is before the Court upon Defendant Medtronic, Inc.'s ("Medtronic" or "Defendant") motion to dismiss the amended complaint filed by Relator Leanne Houston ("Houston" or "Relator") for failure to state a claim upon which relief may be granted pursuant to Rules 8(a) and 12(b)(6) of the Federal Rules of Civil Procedure, and for failure to plead fraud with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. (ECF No. 69.) Relator filed a response in opposition to the motion on November 19, 2024, and Defendant filed a reply on December 4, 2024. (ECF Nos. 78, 81.) The Court held oral argument on May 7, 2025, following which the United States of America ("the government") filed a statement of interest regarding Defendant's motion to dismiss, indicating that it takes no position on the grounds for dismissal raised in Defendant's motion. (ECF No. 84.)

For the following reasons, the Court grants in part and denies in part Defendant's motion to dismiss. Specifically, the Court grants Defendant's motion as to Relator's first

cause of action for violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B), and denies the motion as to Relator's second cause of action for retaliation in violation of 31 U.S.C. § 3730(h).

BACKGROUND

I. Procedural History

Relator filed her initial 163-page *qui tam* complaint against Medtronic and others on September 23, 2020, alleging a total of 42 claims. (ECF No. 1.) On November 22, 2023, the government filed its notice of election to decline intervention, pursuant to the False Claims Act, 31 U.S.C. § 3730(b)(4)(B). (ECF No. 25.) The Court unsealed the action on November 27, 2023, and ordered Relator to serve her complaint on Defendants. (ECF No. 26.)

After being granted multiple extensions of time to serve the complaint, Relator filed a motion to dismiss Defendant McLeod Health, Inc. ("McLeod") with prejudice on July 16, 2024, alleging that "she cannot state a claim against McLeod." (*See* ECF Nos. 37-38, 41, 43, 46-47, 49 at 2, 51-52.) The government filed a response in partial opposition to Relator's motion, indicating that it opposed dismissal of McLeod with prejudice (as opposed to without prejudice) as to the government. (ECF No. 56.) On August 23, 2024, however, Relator filed an amended complaint naming only Medtronic as a Defendant; based on the filing of the amended complaint, the Court entered a text order finding moot Plaintiff's motion to dismiss McLeod. (ECF Nos. 59, 60.)

After being granted an extension of time to answer or otherwise plead in response to the amended complaint, Medtronic filed its motion to dismiss on October 15, 2024. (ECF No. 69.) The matter has been fully briefed and is ripe for review, as outlined above. (*See*

ECF Nos. 69, 78, 79, 84, 85.)

II. Relator's Amended Complaint

In her 31-page amended complaint, Plaintiff, who is a former sales representative for Medtronic, alleges two causes of action: (1) violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B), and (2) retaliation in violation of 31 U.S.C. § 3730(h). (ECF No. 59 at 29-31.) Plaintiff's claims stem from her assertion that Medtronic illegally obtained payment from federal health insurance programs through the fraudulent sale of defective surgical staplers.

According to Plaintiff, in late August 2018, she began reporting concerns raised by surgeons at McLeod about Medtronic's GIA80 surgical staplers, but "Medtronic responded by concealing the defect to avoid a recall, which it did by falsely reporting the adverse incidents to the U.S. Food and Drug Administration (FDA) by telling non-surgeon executives at McLeod that the issue was user error, when it knew that was not the case." (*Id.*) Plaintiff further asserts that she was not willing to conceal the defect and was suspended as a result in October 2018 and was ultimately informed in early December 2018 that she would be terminated for "incompetence." (*Id.* at 2, 26-28.) According to Plaintiff, however, she was the top sales representative in her region at the time of her termination, and she contends that her termination was in retaliation for her reports about the staplers to Medtronic and for her refusal to engage in Medtronic's scheme to promote worthless equipment. (*Id.* at 2, 11-18, 25-28, 30-31.) Plaintiff further contends that Medtronic's fraudulent concealment of the defect in its GIA80 staplers caused injury to patients and caused the government "to pay for services made worthless by the defective surgical staplers, which it would not have paid for had Medtronic not fraudulently concealed

the truth." (*Id.* at 2, 11-22.)

STANDARDS OF REVIEW

The amended complaint asserts a claim under 31 U.S.C. § 3729(a)(1)(A)-(B). Because such a claim under sounds in fraud, it must satisfy both Rule 8(a)'s plausibility requirement and Rule 9(b)'s heightened standard to plead fraud with particularity. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 195 n.6 (2016). The amended complaint also alleges a claim for retaliation under § 3730(h). Unlike substantive claims under the False Claims Act, "retaliation claims under § 3730(h) are not subject to Rule 9(b)'s heightened particularity requirement. Instead, a plaintiff need only satisfy Rule 8(a)'s notice-pleading standard. *U.S. ex rel. Grant v. United Airlines, Inc.*, 912 F.3d 190, 197 (4th Cir. 2018).

A motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6) "challenges the legal sufficiency of a complaint, considered with the assumption that the facts alleged are true." *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009) (internal citations omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Twombly*, 550 U.S. at 556). Although the allegations in a complaint generally must be accepted as true, that principle "is inapplicable to legal conclusions," and the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* (citations

and quotation marks omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* at 678 (quoting *Twombly*, 550 U.S. at 557). Stated differently, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). Still, Rule 12(b)(6) "does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." *Colon Health Centers of Am., LLC v. Hazel*, 733 F.3d 535, 545 (4th Cir. 2013) (quoting *Neitzke v. Williams*, 490 U.S. 319, 327 (1989)).

Rule 9(b) imposes a heightened pleading standard on fraud claims, under which a plaintiff must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The purposes of Rule 9(b) include "providing notice to a defendant of its alleged misconduct," "preventing frivolous suits," "eliminating fraud actions in which all the facts are learned after discovery," and "protecting defendants from harm to their good will and reputation." *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013) (quotation marks and modifications omitted). Rule 9(b)'s particularity requirement "serves as a necessary counterbalance to the gravity and quasi-criminal nature of FCA liability." *Grant*, 912 F.3d at 197 (citations and quotation marks omitted).

DISCUSSION

In its motion to dismiss, Medtronic asserts that the Court should dismiss both claims in Relator's amended complaint. With respect to the first claim for violation of the False

Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B), Medtronic asserts that: (1) Relator fails to plead any facts to establish the falsity of claims as required by the False Claims Act, because the Fourth Circuit has expressly rejected a "fraud on the FDA" theory of liability: (2) even if the Court accepts Relator's characterization of her claim as a "worthless services" claim (rather than a "fraud on the FDA" claim), Relator fails to meet the basic pleading requirements to establish falsity and materiality; and (3) any claims regarding Medtronic's staplers are barred by the public disclosure bar. (ECF No. 69-1 at 9-27.)

Next, with respect to Relator's second claim for retaliation in violation of 31 U.S.C. § 3730(h), Medtronic asserts that Relator fails to plead a cognizable claim because Relator's alleged conduct does not constitute protected activity and because Relator's allegations concerning Medtronic's knowledge are insufficient, such that Medtronic could not have retaliated against her within the meaning of § 3730(h).

In response to Medtronic's motion, Relator first argues that Medtronic's "fraud on the FDA" argument is a strawman argument because Relator does not assert such a claim; rather, Relator contends that she asserts a worthless services claim. (ECF No. 78 at 18.) According to Relator: "Medtronic caused McLeod to present claims to the government for payment for worthless surgical services by knowingly selling defective surgical staplers to McLeod. The defective staplers made the surgical services worthless because they caused acute injury to government-beneficiary patients requiring further medical care at Government expense." (*Id.*) Relator contends that the amended complaint sufficiently pleads a worthless services claim, explaining: "[t]he procedures performed at McLeod using the GIA80 stapler in and after August 2018 were not 'reasonable and necessary' under the Government's definition of the phrase because they were not 'safe and effective' nor

'furnished in accordance with accepted standards of medical practice.'" (ECF No. 78 at 24 (citation omitted).)

In all, Relator contends that the amended complaint sets forth a plausible worthless services claim with particularity as to time, place, content, and materiality. Relator further contends that her first cause of action is not barred by the public disclosure bar because Medtronic has not identified any public disclosure of the alleged manufacturing defect with the GIA80 staplers at issue, much less any prior public disclosure of an alleged fraudulent scheme regarding such. (*Id.* at 27.) Finally, as to her first cause of action, Relator contends that she is an original source of information. (*Id.* at 29.)

Next, with respect to her second claim for retaliation in violation of § 3730(h), Relator asserts that the amended complaint includes sufficient facts to support a reasonable inference: (1) that she engaged in protected activity; (2) that Medtronic knew about the protected activity; and (3) that Medtronic took an adverse action against her as a result of her protected activity. (*Id.* at 29-32.)

I. Relator's Claim for Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B)

The False Claims Act allows private litigants to bring actions on behalf of the government against anyone who, *inter alia*, "knowingly presents, or causes to be presented, [to the government] a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). "In general, a False Claims Act relator is required to allege four elements: (1) 'there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that

was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)'" *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 188 (4th Cir. 2022) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999)). "Failure to adequately allege any of these elements dooms a claim." *Id.*

In its motion to dismiss, Medtronic first asserts that Relator's claim for violation of the False Claims Act is, in fact, a "fraud on the FDA" claim that fails in the Fourth Circuit as a matter of law in light of *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (finding that FDA regulatory violations fail to support liability under the False Claims Act).

After review, the Court agrees with Medtronic that, to the extent Relator relies on alleged FDA violations, such allegations do not satisfy the False Claims Act's falsity element as a matter of law.[1] *See Rostholder*, 745 F.3d at 694; *see also Escobar*, 579 U.S. at 194 (holding that the False Claims Act is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations"); *Harrison*, 176 F.3d at 786-87 (discussing *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir.1997), and stating that FCA liability based on a false certification to the government "will lie only if compliance with the statutes or regulations was a prerequisite to gaining a benefit, and the defendant affirmatively certified such compliance"). Thus, the Court finds that Relator's reliance on the staplers' alleged non-compliance with FDA requirements fails to

[1] The Court disagrees with Relator that *Rostholder* is inapposite. Instead, the Court finds *Rostholder* persuasive because it involves manufacturing considerations similar to Relator's allegations regarding an alleged manufacturing defect in Medtronic's GIA80 staplers. *See Rostholder*, 745 F.3d at 701-02 (finding that "once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated because of having been processed in violation of FDA safety regulations").

support liability under the False Claims Act.

As previously mentioned, Relator asserts in response to Medtronic's motion that she does not intend to allege a "fraud on the FDA" claim, but rather, a worthless services claim. Even assessing Relator's claim under a worthless services theory, however, the Court finds the allegations in the amended complaint insufficient to satisfy both Rule 8(a)'s plausibility requirement and Rule 9(b)'s heightened standard to plead fraud with particularity.

As an initial matter, although the Fourth Circuit did not address the worthless services theory in *Rostholder*, it cited to a case from the Second Circuit Court of Appeals, where the Second Circuit described the worthless services theory as follows: "It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. [ ] In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001) (internal citation omitted); *see also Rostholder*, 745 F.3d at 702 n. 7 (citing *Mikes*); and *United States ex rel. Davis v. U.S. Training Ctr. Inc.*, 498 F. App'x 308, 315 n. 11 (4th Cir. Dec. 6, 2012) (setting forth the description of the worthless services theory set forth in *Mikes*).

Here, the parties agree that Medicare's general standard for coverage of a surgical procedure is that it must be "reasonable and necessary." 42 U.S.C. § 1395y. Relator asserts in response to Defendant's motion that she has sufficiently alleged that the surgeries at issue were not reasonable and necessary.[2] (ECF No. 78 at 22.) In support,

[2] The Court notes that Relator's response to Medtronic's motion also references new theories of liability, but as Medtronic points out in its reply, a complaint "may not be amended by the briefs in opposition to a motion to dismiss." *Harley v. S.C. Dep't of Corr.*, 2017 WL 2839634, at *1 (D.S.C. June 30, 2017). The Court thus confines its review to the specific allegations in the amended complaint.

she cites to paragraph 116 of the amended complaint, which provides:

> The services were worthless because, in the face of full disclosure of all relevant facts, neither the Government nor anyone else would buy the service at any price. No one would purchase a colon resection, for example, from a provider who disclosed that he would use defective tissue staplers causing major bleeding issues and requiring follow up surgery to correct. Everyone would instead purchase the needed service from someone using non-defective surgical tools. The market value of the defective service is zero because no fully informed buyer would agree to pay for it. To get anyone to agree to pay for it requires fraud.

(*Id.* (quoting ECF No. 59 ¶ 116).) In addition, Relator urges the Court to consider cases addressing worthless services claims in the context of nursing homes.[3] (*See id.* at 23 (citing cases).)

After review, the Court finds Relator's arguments unavailing. Importantly, nowhere in paragraph 116 or elsewhere in the amended complaint does Relator allege any facts to demonstrate that government insurers would not have paid for the surgical procedures using the allegedly defective staplers. In other words, nowhere does Relator allege facts to show that the use of the Medtronic staplers had any relevance to a government insurer's condition of payment for the surgeries. In fact, Relator admits that "the use of a stapler, which but for Medtronic's noncompliance with regulations would have been subject to a recall, would not be, in itself, material to Medicare or Medicaid's decision to pay for an appendectomy or other surgical procedure using that stapler." (ECF No. 19 at 33.) Taking it one step further, Relator also does not allege that the use of Medtronic staplers had any bearing on a surgeon's determination that a surgery was medically necessary.

[3] The Court finds Relator's reliance on nursing home cases misplaced because the worthless services theory in those cases involves a standard for payment and coverage that differsgreatly from the standard that applies to surgical services.

In all, the Court is simply not convinced by Relator's argument that the use of Medtronic staplers, which caused complications, completely voided the reasonableness and necessity of a government insurer's payment of money for the surgical procedures. In light of the foregoing, the Court finds that the amended complaint fails to set forth sufficient factual allegations of falsity and materiality to satisfy the heightened Rule 9(b) standard that applies to Relator's first cause of action for violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B). Accordingly, the Court grants Defendant's motion to dismiss as to this claim.

II. Relator's Claim for Retaliation in violation of 31 U.S.C. § 3730(h)

To sufficiently plead a § 3730(h) retaliation claim and thus survive a motion to dismiss, a plaintiff must allege facts sufficient to support a "reasonable inference" of three elements: (1) she engaged in protected activity; (2) her employer knew about the protected activity; and (3) her employer took adverse action against her as a result. *See Iqbal*, 556 U.S. at 678; *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 433 (4th Cir. 2015). As to the first element, § 3730(h) defines two types of protected activity–acts "in furtherance of an [FCA action]" (the "first prong"), or "other efforts to stop 1 or more [FCA violations]" (the "second prong"). 31 U.S.C. § 3730(h)(1).

After review, the Court finds that, under the objective reasonableness standard that governs the second prong of protected activity, Relator's amended complaint sufficiently alleges that she engaged in protected activity where she had an objectively reasonable belief that Medtronic's conduct violated the False Claims Act and that her actions were designed to stop at least one violation of the False Claims Act. Here, the amended complaint alleges that Relator expressed concerns to Medtronic on multiple occasions

about the complaints she received from surgeons regarding the GIA80 staplers and that Relator refused to agree with Medtronic that the issue with the staplers was due to user error. Relator further alleges that her manager's boss yelled at her and said "he didn't ever want to hear her discuss the possibility of a lot number issue with the GIA80 stapler again, that she was putting the 'conversion' at risk." (ECF No. 59 at 21.) Accepting the facts alleged by Relator as true, the Court finds that it was objectively reasonable for Relator to believe that Medtronic's conduct was fraudulent and that her actions were designed to stop one or more violations of the False Claims Act.

Additionally, as to the second element of her § 3730(h) retaliation claim, the Court finds that the amended complaint sufficiently pleads that Medtronic knew about Relator's protected activity. For example, Relator alleges that seven separate surgeons informed her of issues with the staplers, and that she then reported each of the complaints to her managers at Medtronic and completed internal company paperwork, copies of which are attached to the amended complaint. (ECF Nos. 59 at 15; 59-3.) Also according to the amended complaint, "[m]ore than 31 documented text messages, videos of patients bleeding during surgery, voicemails from customers, hospital complaint forms for each incident, and emails were sent." (ECF No. 59 at 16-17.) In all, the Court finds the allegations of the amended complaint sufficient to satisfy the knowledge prong.

With respect to the third element, "[a]n employer undertakes a materially adverse action opening it to retaliation liability if it does something that 'well might have dissuaded a reasonable worker from making or supporting a charge of discrimination.'" *Smith*, 796 F.3d at 434 (quoting *Burlington N. & Santa Fe Ry. v. White*, 548 U.S. 53, 67-68 (2006). Here, Relator alleges that she was suspended and ultimately terminated as a result of her

protected activity, and the Court finds Relator's allegations sufficient to satisfy the adverse action prong. *See*, *e.g.*, *United States ex rel. Grant*, 912 F.3d at 203 ("Here, Grant's termination, following close on the heels of his numerous complains, represents the ultimate action that an employer can take against a reasonable worker for whistleblowing.").

Accordingly, the Court finds that Relator's amended complaint sufficiently pleads a claim of retaliation under § 3730(h) to satisfy Rule 8(a)'s notice-pleading standard. Therefore, the Court denies Defendant's motion to dismiss with respect to Relator's second cause of action for retaliation in violation of § 3730(h).

CONCLUSION

Based on the foregoing, the Court grants in part and denies in part Medtronic's motion to dismiss (ECF No. 69). Specifically, the Court grants the motion with respect to Relator's first cause of action for violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B), and the Court denies the motion with respect to Relator's second cause of action for retaliation in violation of 31 U.S.C. § 3730(h).

IT IS SO ORDERED.

/s/Bruce H. Hendricks
United States District Judge

June 20, 2025
Charleston, South Carolina